

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION

MORTON GROVE	)	
PHARMACEUTICALS, INC.	)	
	)	
Plaintiff,	)	
	)	No: 08-CV-1384
v.	)	
	)	Judge Bucklo
THE NATIONAL PEDICULOSIS	)	Magistrate Judge Mason
ASSOCIATION, INC.	)	
	)	
Defendants.	)	
	)	

**PLAINTIFF MORTON GROVE PHARMACEUTICALS, INC.’S REPLY IN  
SUPPORT OF ITS MOTION FOR LEAVE TO FILE AMENDED COMPLAINT**

This motion relates to Morton Grove’s routine effort to amend its complaint. Morton Grove seeks to modify just six paragraphs in its 20 page complaint. Morton Grove’s amendment adds no new causes of action, nor does it put any additional false statements at issue that were not previously plead. This amendment simply adds additional context to Morton Grove’s prior allegations—something, as described in greater detail below, this Court must consider under controlling Lanham Act case law.

The NPA’s response brief makes much ado (13 pages) about nothing. The NPA takes a strained and implausible reading of Morton Grove’s amendment and complains that it “would vastly expand Morton Grove’s claims” and is based on the NPA’s protected petitioning of the FDA. To the contrary, Morton Grove’s amendment simply provides more details about the claims already stated. For example, the NPA argues that Morton Grove is bringing suit because of the NPA’s submission of MedWatch forms to the FDA. Morton Grove has amended its complaint consistent with the evidence to note that the NPA includes on its promotional

website assertions that it is a “Health Professional”—the same point contained in Paragraph 2 of Morton Grove’s current complaint (the NPA “masquerades as a health organization”). As discussed below, the NPA has taken its FDA submissions where it claims to be a “Health Professional” and posted them on its commercial website in an effort to influence consumers. In fact, the NPA does not and has never employed a single licensed healthcare professional. As Morton Grove explained further in its proposed amendment, these representations “contribute to the illusion of medical credentials that the NPA projects on its website, and are part of the context in which the NPA’s false statements were made.” This is the basis for Morton Grove’s contextual amendment, which is routine and should be freely allowed.

### **ARGUMENT**

The standard here is clear: “Rule 15(a) declares that leave to amend ‘shall be freely given when justice so requires’; this mandate is to be heeded.” *Foman v. Davis*, 371 U.S. 178, 182 (1962). Where Morton Grove adequately pled its claim so that it put NPA on notice and where there is no prejudice to NPA, Morton Grove “ought to be afforded an opportunity to test [its] claim on the merits.” *Id.*

#### **I. MORTON GROVE’S PROPOSED AMENDMENT ADDS NO NEW CLAIMS AND PROPERLY PROVIDES CONTEXT FOR THE STATEMENTS AT ISSUE**

##### **A. *Morton Grove’s Amendments Do Not Add Additional False and Misleading Statements***

Contrary to the NPA’s unsupported allegations, Morton Grove’s proposed amended complaint puts no new false and misleading statements at issue. Rather, Morton Grove’s claims continue to be based on the same dozen statements outlined in Morton Grove’s initial pleading. (*See* Amended Cmplt. Redlined Version Dkt. No. 77-2, Ex. 2.) These statements are highlighted in Section II of the pleading entitled “The NPA Attempts to Increase

Sales of the LiceMeister® by Distributing False, Misleading, and Deceptive Advertisements Regarding Lindane. *See* Amended Cmplt. ¶¶ 26, 28, 29, 36, 40, 41, 43, and 44, Dkt. No. 77-2, Ex. 1.) It is apparent on the face of the pleading that Morton Grove’s claims are based on these statements, which have previously been identified with particularity and already survived a motion to dismiss.

**B. *Morton Grove’s Amendments Properly Provide Context For the NPA’s False and Misleading Statements***

Critical to understanding the misleading nature of the NPA’s statements, the amendments provide additional context for Morton Grove’s previously stated claims. *See Am. Hardware Mfrs. Ass’n v. Reed Elsevier, Inc.*, No. 03 C 9421, 2006 WL 1895731, at \*2 (N.D. Ill. July 6, 2006) (granting motion to amend and explaining that “[f]avoring [plaintiff] is the fact that its proposed amendments present new factual allegations that support previously asserted theories, rather than new legal theories.”) (App. Tab 1).

The context for the NPA’s false statements has always been a part of the case just as it is in any Lanham Act case. None of the points that the NPA complains of are altogether new. As stated in the current version of the Complaint:

- Defendant NPA is the distributor of the LiceMeister® Comb, which competes with Lindane medications. While the NPA refers to itself as an “agency dedicated to protecting children from the misuse and abuse of potentially harmful lice and scabies pesticidal treatments” ***and masquerades as a health organization***, upon information and belief, the NPA does not employ a single physician or licensed health professional. It is a competitor of Morton Grove. (Cmplt. ¶ 2 (emphasis supplied).)
- Despite this well-documented scientific, medical, and regulatory history, the NPA has launched an attack campaign on Lindane medications. The NPA swaps agricultural and pharmaceutical research, selectively quoting and/or misstating findings from studies relating to the agricultural use of lindane, and widely disseminates false, misleading, and deceptive statements about the safety profile and effectiveness of Lindane medications. These statements have created confusion in the marketplace

and affected purchasing and prescribing behavior, negatively impacting both the sale of Lindane medications and Morton Grove's business. (Cmplt. ¶ 11.)

- The NPA widely distributed information and products nationally, including in Illinois, through its interactive websites [www.headlice.org](http://www.headlice.org) and [www.lindane.org](http://www.lindane.org), which attract as many as 100,000 hits per day from thousands of unique visitors in the United States and around the world. (Cmplt. ¶ 13.)
- Blindly ignoring well-established science and the positions of the FDA, EPA, CDC, and APA on Lindane medications, ***the NPA has launched an attack campaign against Lindane medications*** in the hopes that it can increase sales of the LiceMeister® comb. This for-profit campaign blatantly ignores all standards for comparative marketing, including those promulgated by the FDA's Division of Drug Marketing and Advertising, which prohibit all such advertisements unless the representations made in those advertisements are supported by substantial evidence derived from adequate and well-controlled studies. *See* 21 U.S.C. § 355(d). Examples of the NPA's false advertising claims and other false statements referenced infra are attached as Exhibit A. (Cmplt. ¶ 22 (emphasis supplied).)
- The NPA's advertising claims set forth above are false and misleading descriptions and representations of fact about Lindane medications. In addition, ***these statements are misleading in context*** and violate Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a). (Cmplt. ¶ 56 (emphasis supplied).)

Thus, the context for the website and the NPA's deceptive representations about its medical credential are well within the scope of Morton Grove's current complaint. The NPA cannot reasonably claim unfair surprise.

On the NPA's commercial website (which contains all the false statements at issue), the NPA receives over a million visitors per year and has sold many millions of dollars of its competing product, the LiceMeister comb. The website is voluminous and each of the false statements at issue are not usually seen in isolation, but rather navigated to through a series of clicks on the site. As such, it is appropriate to examine the content of the pathways through which viewers may move from the NPA's homepage to the false statements at issue. In short,

the overall context and message of the NPA's website is important in the consumer deception inquiry. *Abbot Labs. v. Mead Johnson & Co.*, 971 F.2d 6, 15 (7th Cir. 1992) ("The presence of this implied message is even more pronounced when viewed *in the context of [defendant's] entire promotional campaign*") (emphasis added). In fact, courts have found it to be reversible error not to consider the full context of an advertisement. *See Avis Rent A Car System, Inc. v. Hertz Corp.*, 782 F.2d 381, 385-86 (2d Cir. 1986) (reversing district court because interpretation of advertisement did not consider the context of the advertisement, which mentioned renting multiple times).

**C. *The NPA's Misrepresentation of Its Status As A "Health Professional" Is Not Based on the NPA's Submissions to FDA, But Rather On The NPA's Commercial Website***

As discussed above, Morton Grove is *not* asserting new legal claims<sup>1</sup> predicated on the NPA's submission of false MedWatch forms to the FDA. (NPA Br. at 10-12.) Rather, Morton Grove is making clear it is relying on FDA forms prominently highlighted by the NPA on its commercial website (see <http://www.headlice.org/report/mwreport.html>) in relation to Morton Grove's long-standing allegation that the NPA "masquerades as a health organization." On its website, the NPA identifies itself to consumers who are deciding whether to purchase Lindane medication or the NPA's product as a "Health Professional"—this is an important fact in the deception analysis.

At base, when considering a false statement and its impact on consumer perception, the perceived identity and perceived credentials of the party making the statement would be relevant to consumer perception and ultimate deception. False impressions and

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<sup>1</sup> This would be akin to making a false statement to a governmental agency—a criminal claim—which is not Morton Grove's theory. Rather, the issue goes to Morton Grove's Lanham Act case and the context for consumer perception about the information viewed.

misrepresentations<sup>2</sup> about the identity of the speaker are material to and contribute to the consumer believing, erroneously, that the NPA is an organization who employs licensed healthcare professionals—which is relevant to what consumers would think of the information presented. But, nowhere does Morton Grove allege a claim against NPA based on the NPA’s false submission of MedWatch forms to the FDA. All Morton Grove alleges is the NPA’s act of denoting itself a “Health Professional” on its commercial website where its sells millions of dollars of a competing product provides context for why consumer’s are likely to be deceived by the false and misleading statements that have long been at issue in this action.

## **II. MORTON GROVE’S AMENDMENT WAS NOT PROPOSED IN BAD FAITH AND CAUSES NO PREJUDICE**

### **A. *Morton Grove’s Amendment Is Not Harassing***

NPA’s assertion that Morton Grove has a “bad-faith purpose of harassing NPA in retaliation for filing MedWatch forms and chilling NPA’s future submissions” is baseless and insulting. (NPA Br. at 5-6.) NPA drags on for over a page that there can be no liability for a party’s petitioning of the government. But, because Morton Grove’s amendments are not based on the NPA’s submissions to FDA, but rather the NPA’s commercial website (this is apparent from the face of the pleading and Morton Grove’s opening and reply briefs), it is hard to fathom how Morton Grove’s contextual amendments are harassing or futile. The NPA’s 13 pages of chest-thumping do nothing to demonstrate otherwise.

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<sup>2</sup> This is a misrepresentation that the NPA cannot even credibly dispute. The MedWatch form instructions provide the following information on “Health Professional”: “Please indicate whether you are a health professional (e.g. physician, pharmacist, nurse, etc.) or not. If you are not a health professional, please complete block G3 by filling in NA.” United States Food & Drug Administration, *Instructions for Completing the MedWatch Form 3500* (emphasis added), available at [http://www.fda.gov/medwatch/REPORT/CONSUMER/INSTRUCT.HTM#SECTION\\_G](http://www.fda.gov/medwatch/REPORT/CONSUMER/INSTRUCT.HTM#SECTION_G).

**B. *The NPA Will Not Be Prejudiced By The Amendments***

The NPA does not and cannot articulate how it would be prejudiced by this amendment. Delay is rarely a valid reason to reject an amendment of the pleadings and is only a sufficient basis when such delay will cause undue prejudice. *Dubicz v. Commonwealth Edison Co.*, 377 F.3d 787, 793 (7th Cir. 2004) (reversing district court for denying motion to amend because “delay by itself is normally an insufficient reason to deny a motion for leave to amend”) (citation omitted).

Because Morton Grove’s amendment adds no new claims or parties and will not result in any substantial additional discovery, it is hard to fathom how the NPA could suffer any prejudice. Even if some additional discovery was necessary (Morton Grove does not believe it is), the NPA is not prejudiced as sufficient time remains before the October 1, 2008 close of fact discovery. *See Am. Broad. Co. v. Maljack Prods., Inc.*, No. 97 C 6510, 1998 WL 325209, at \*3 (N.D. Ill. June 9, 1998) (granting leave to amend because “the mere necessity of new discovery does not rise to the level of undue prejudice”) (App. Tab 2).

The NPA next complains that the facts which form the basis for the amendment were previously known to Morton Grove. Morton Grove disputes this as a factual matter. For example, while Morton Grove previously knew that the NPA held itself out as a “Health Professional,” deposition discovery confirmed this statement to be utterly fraudulent. In any event, this factual dispute is largely legally irrelevant as prior knowledge is generally a legally insufficient basis upon which to deny a motion to amend. *See Am. Hardware Mfrs. Ass’n*, 2006 WL 1895731, at \*4 (“While it is difficult to condone [plaintiff’s] delay in alleging information it presumably had access to even before it filed its complaint, denying [plaintiff’s] motion to amend is not appropriate.”). Furthermore, even if the parties had long known the factual basis

for these amendments, that fact (if true) belies the NPA's argument of prejudice. *See Serfecz v. Jewell Food Stores, Inc.*, No. 92 C 4171, 1997 WL 543116, at \*4 (N.D. Ill. Sept. 2, 1997) (“[Defendant’s] argument that the facts underlying [Plaintiff’s] waste claim have been well known for years is something of a double-edged sword. For [Defendant], too, has been aware of the alleged basis of Count V since [Plaintiff] added the count in July 1996 (if not before). The proposed amendment should hardly catch [Defendant] by surprise, and “[w]here the facts on which a previously unasserted claim is based are all known or available to all parties, no prejudice exists.”) (internal citations omitted) (App. Tab 3).

### **CONCLUSION**

Morton Grove's motion to amend is routine and should be freely granted—it alters just a handful of paragraphs, adds no new claims, no new parties, and puts no additional false statements at issue. The amendment is not futile or harassing and the NPA will not be prejudiced as a result of the granting of this motion.

Dated: August 15, 2008

Respectfully Submitted,

**MORTON GROVE PHARMACEUTICALS, INC.**

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**CERTIFICATE OF SERVICE**

I hereby certify that on this 15th day of August 2008, I caused a copy of **Morton Grove Pharmaceuticals, Inc.'s Reply In Support of Its Motion for Leave to File Amended Complaint** to be served on counsel of record via ECF electronic filing:

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